162314



PATENT Customer No. 22,852 Attorney Docket No. 07680.0031-00000

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	) CONFIRMATION NO.: 8638
YUNXIANG, ZHU	, )
Application No.: 10/051,711	) Group Art Unit: 1623 )
Filed: January 17, 2002	)    Examiner: KHARE, DEVESH ) )
For: METHODS FOR INTRODUCING MANNOSE-6-PHOSPHATE AND OTHER OLIGOSACCHARIDES ONTO GLYCOPROTEINS (As Amended)	, ) ) )

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

### INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicant brings to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

Copies of the listed foreign and non-patent literature documents are attached.

Copies of the U.S. patent publications are not enclosed.

05/16/2005 HALI11 00000066 060916 10051711 01 FC:1806 180.00 DA

PATENT Customer No. 22,852 Attorney Docket No. 07680.0031-00000

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claims in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Bv:

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: May 13, 2005

ě

Konstantin M. Linnik Reg. No. 56,309

Tel. (617) 452-1626

IDS Form PTO/SB/08: Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of

•	Complete if Knowi	DIPA
Application Number	10/051,711	10 61
Filing Date	January 17, 2002	
First Named Inventor	Zhu Yunxiang	MAY 1 3 2005
Art Unit	1623	3
Examiner Name	Devesh, Khare	
Attorney Docket Number	07680.0031-00000	PANCUSPAS

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner	Cite	Cite Document Number Issue or Publication Date MM-DD-YYYY		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
Initials	No.		Applicant of Cited Document	Figures Appear	
		US- 2002/0025550 A1	02/28/2002	Canfield	
_		US- 2004/0006008 A1	01/08/2004	Lebowitz et al.	
		US- 2004/0132640 A1	07/08/2004	DeFrees et al.	
		US- 2005/0026823 A1	02/03/2005	Zankel et al.	
		US- 2005/0058634 A1	03/17/2005	Yunxiang Zhu	
		US- 2002/0137125 A1	09/26/2002	Yunxiang Zhu	
		US- 2003/0119088 A1	06/26/2003	Canfield et al.	
		US- 2005/0003486 A1	01/06/2005	Canfield et al.	
		US- 6,534,300	03/18/2003	Canfield	
		US- 6,670,165	12/30/2003	Canfield	-
		US- 6,861,242	03/01/2005	Canfield	
		US- 6,537,785	03/25/2003	Canfield	
<del> </del>		US- 6,642,038	11/04/2003	Canfield	
		US- 6,770,468	08/03/2004	Canfield	
		US- 6,828,135	12/07/2004	Canfield	
		US- 6,800,472	10/05/2004	Canfield et al.	

Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

	FOREIGN PATENT DOCUMENTS							
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>8</sup>		

	NON PATENT LITERATURE DOCUMENTS		
		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation 6
	_	AMALFITANO et al., "Systemic Correction of the Muscle Disorder Glycogen Storage Disease Type II After Hepatic Targeting of a Modified Adenovirus Vector Encoding Human Acid-α-Glucosidase," <i>Proc. Natl. Acad. Sci. USA</i> , 96:8861-8866 (1999)	
		ARAKATSU et al., "V. Specificity and Cross-Reactivity with Dextrans of the Antibodies Formed in Rabbits to Isomaltonic and Isomaltotrionic Acids Coupled to Bovine Serum Albumin," Immunochemical Studies on Dextrans, The Journal of Immunology, Vol. 97, No. 8 (1966).	
		BERNSTEIN et al., "A general synthesis of model glycoproteins: coupling of alkenyl glycosides to proteins, using reductive ozonolysis followed by reductive amination with sodium cyanoborohydride," Carbohydrate Research, Vol. 78, C1-C3 (1980).	

IDS Form PTO/SB/08: Substitute for form 1449A/PTO

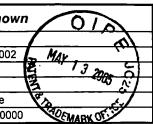
ł

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	2	of	3

Application Number 10/051,711
Filing Date January 17, 2002
First Named Inventor Zhu Yunxiang
Art Unit 1623
Examiner Name Devesh, Khare
Attorney Docket Number 07680.0031-00000



NON PATENT LITERATURE DOCUMENTS	
 BIJVOET et al., "Generalized Glycogen Storage and Cardiomegaly in a Knockout Mouse Model of Pompe Disease," Human Molecular Genetics, Vol. 7 No. 1 (1998)	-
CHAUDHARI et al., "Coupling of Amino Acids and Amino Sugars with Cyanuric Chloride (2,4,6-Trichloro-s-triazine), Can. J. Chem., Vol. 50, No. 13 (1972).	. 10.00
CHEN et al., "Towards a Molecular Therapy for Glycogen Storage Disease Type II (Pompe Disease))," Molecular Medicine Today, Vol. 6, Issue 6, pp. 245-251 (2000)	
DAVIS, "Recent Developments in Glycoconjugates," J. Chem. Soc., Vol. 1, pp. 3215-3237 (1999)	
DAVIS, "Synthesis of Glycoproteins," Chem. Rev., Vol. 102, pp. 579-601 (2002)	
DAVIS et al., "Glycoprotein Synthesis: From Glycobiological Tools to Tailor-Made Catalysts," Synlett 9:1495-1507 (1999).	
Fielder et al., "An Immunogenic Polysaccharide-Protein Conjugate," J. Immunol., Vol. 105, No. 1 (1970)	
FURBISH et al., "Uptake and Distribution of Placental Glucocerebrosidase in Rat Hepatic Cells and Effects of Sequential Deglycosylation," Biochim. Biophys. Acta, Vol. 673, pp. 425-434 (1981)	
GRAY, "The Direct Coupling of Oligosaccharides to Proteins and Derivatized Gels," Archives of Biochemistry and Biophysics, Vol. 163, pp. 426-428 (1974).	
Helenius et al., "Intracellular Functions of N-Linked Glycans," Science Magazine, Vol. 291 (2001)	
HIMMELSPACH et al., "Use of 1-(m-aminophenyl)flavazoles for the preparation of immunogens with oligosaccharide determinant groups," Eur. J. Immunol., Vol. 106, No. 1 (1971).	
King et al., "Preparation of Protein Conjugates via Intermolecular Hydrazone Linkage," Biochemistry 25:5774-5779 (1986).	
KLEINHAMMER et al., "Synthesis and immunological properties of an artificial antigen with the repeating oligosaccharide unit of <i>Salmonella illinois</i> as haptenic group," Eur. J. Immunol., Vol. 3, pp. 834-838 (1973).	
LEE et al., "2-Imino-2-Methoxyethyl 1-Thioglycosides: New Reagents for Attaching Sugars to Proteins," Biochemistry 15:3956-3963 (1976).	
Lee et al., "A Biochemical and Pharmacological Comparison of Enzyme Replacement Therapies for the Glycolipid Storage Disorder Fabry Disease," Glycobiology Vol. 13, No. 4, pp. 305-313 (2003)	
LEMIEUX et al., "The Properties of a "Synthetic" Antigen Related to the Human Blood-Group Lewis a," J. of the American Chem. Society, pp. 4076-4083 (1975)	
LI et al., "Isolation and Characterization of Mannose 6-Phosphate/Insulin-Like Growth Factor II Receptor from Bovine Serum," <i>Glycobiol.</i> , 1:511-517 (1991)	
MATSUURA et al., "Human a-galactosidase A: characterization of the N-linked oligosaccharides on the intracellular and secreted glycoforms overexpressed by Chinese hamster ovary cells," Glycobiology Vol. 8 No. 4, pp. 329-339 (1998)	
MCBROOM et al., "Carbohydrate Antigens: Coupling of Carbohydrates to Proteins by Diazonium and Phenylisothiocyanate Reactions," Methods in Enzymology Volume XXVII, Complete Carbohydrates, Part B 212-222 (1972).	
 MOCZAR et al., "Preparation of N-Acetylglucosamine Derivatives of Proteins," FEBS Letters Vol. 50 No. 3 (1975)	
MONTALVO et al., "Glycogenesis type II: identification and expression of three novel mutations in the acid a- glucosidase gene causing the infantile form of the disease," Elsevier Inc., Molecular Genetics and Metabolism 81, pp. 203-208 (2004)	
MORELAND et al., "Lysosomal Acid a-Glucosidase Consists of Four Different Peptides Processed from a Single Chain Precursor," J. Biol. Chem., Vol. 280 No. 8, pp. 6780-6791 (2005)	
Orr et al., "Synthetic Concanavalin A Receptors and Erythrocyte Agglutination," Nature 272:722-725 (1978).	
RABEN et al., "Enzyme Replacement Therapy in the Mouse Model of Pompe Disease," Molecular Genetics and Metabolism Vol. 80, pp. 159-169 (2003)	-
RABEN et al., "Glycogen Stored in Skeletal but Not in Cardiac Muscle in Acid α-Glucosidase Mutant (Pompe) Mice is Highly Resistant to Transgene-Encoded Human Enzyme," Mol. Ther., 6:601-608 (2002)	
RABEN et al., "Replacing Acid a-Glucosidase in Pompe Disease: Recombinant and Transgenic Enzymes are Equipotent, but Neither Completely Clears Glycogen from Type II Muscle Fibers," Molecular Therapy Vol. 11, No. 1 (2005)	
RABEN et al., "Targeted Disruption of the Acid α-Glucosidase Gene in Mice Causes an Illness with Critical Features of Both Infantile and Adult Human Glycogen Storage Disease Type II," J. Biol. Chem., 273:19086-19092 (1998)	

IDS Form PTO/SB/08: Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of

-	С	omplete if Knowi	
	Application Number	10/051,711	MAY.
	Filing Date	January 17, 2002	3 200 O
	First Named Inventor	Zhu Yunxiang	2 W A
	Art Unit	1623	(4)
	Examiner Name	Devesh, Khare	EMARK OF
	Attorney Docket Number	07680.0031-00000	

NON PATENT LITERATURE DOCUMENTS	
REUSER et al., "Uptake and Stability of Human and Bovine Acid a-Glucosidase in Cultured Fibroblasts and Skeletal Muscle Cells from Glycogenosis Type II Patients," Experimental Cell Research, Vol. 155. Issue 1, pp. 178-189 (1984)	
RODWELL et al., "Site-specific covalent modification of monoclonal antibodies: In vitro and in vivo evaluations," Proc. Natl. Acad. Sci. USA, Vol. 83, pp. 2632-2636 (1986).	
Schwartz et al., "Preparation of Hydrazino-Modified Proteins and Their Use for the Synthesis of <sup>99n</sup> Tc-Protein Conjugates," Bioconjugate Chem., Vol. 2, pp. 333-336 (1991)	
SEARS et al., "Toward Automated Synthesis of Oligosaccharides and Glycoproteins," Science Vol. 291 (2001)	
 TANG et al., "Novel Approach to the Study of the Antigenicities and Receptor Functions of Carbohydrate Chains of Glycoproteins," Biochemical and Biophysical Research Communications 132:474-480 (1985).	
TOWNSEND et al., "Analysis of Glycoprotein Oligosaccharides Using High-pH Anion Exchange Chromatography," Glycobiol., 1:139-147 (1991)	
VALENZANO et al., "Soluble Insulin-Like Growth Factor II/Mannose 6-Phosphate Receptor Carries Multiple High Molecular Weight Forms of Insulin-Like Growth Factor II in Fetal Bovine Serum," J. Biol. Chem., 270:16441-16448 (1995)	
VAN HOVE et al., "High-Level Production of Recombinant Human Lysosomal Acid α-Glucosidase in Chinese Hamster Ovary Cells Which Targets to Heart Muscle and Corrects Glycogen Accumulation in Fibroblasts from Patients with Pompe Disease," <i>Proc. Natl. Acad. Sci USA</i> , 93:65-70 (1996)	
VARKI et al., "Structural Studies of Phosphorylated High Mannose-Type Oligosaccharides," J. Biol. Chem., 255:10847-10858 (1980)	
WADHWA et al., "Receptor Mediated Glycotargeting," J. Drug Targeting, Vol. 11 (5), pp. 255-268 (2003)	
YAMAZAKI et al., "Endogenous Lectins as Targets for Drug Delivery," Advanced Drug Delivery Reviews Vol. 43, pp. 225-244 (2000)	
 ZHANG et al., "Linking Carbohydrates to Proteins Using N-(2,2-Dimethoxyethyl)-6-hydroxy Hexanamide," Tetrahedron Vol. 54, pp. 11783-11792 (1998)	
ZHAO et al., "Purification and Characterization of Recombinant Human α-N-Acetylglucominidase Secreted by Chinese Hamster Ovary Cells," Protein Expression and Purification, Vol. 19, pp. 202-211 (2000)	
ZHOU et al., "Mannose 6-Phosphate Quantitation in Glycoproteins Using High-pH Anion-Exchange Chromatography with Pulsed Amperometric Detection," <i>Anal. Biochem.</i> , 306:163-170 (2002)	
ZHU et al., "Carbohydrate-remodeled acid a-glucosidase with higher affinity for the cation-independent mannose 6-phosphate receptor demonstrates improved delivery to muscles of Pompe mice," Biochemical Journal Immediate Publication (2005).	
ZHU et al., "Conjugation of Mannose 6-Phosphate-containing Oligosaccharides to Acid α-Glucosidase Improves the Clearance of Glycogen in Pompe Mice," The Journal of Biological Chemistry, Vol. 279, No. 48, pp. 50336-50341 (2004).	

Examiner	Date			
Signature	Consider	ed		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.